

**Translation**

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PATENT COOPERATION TREATY



# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>F05</b>	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. <b>PCT/JP2003/009370</b>	International filing date (day/month/year) <b>23 July 2003 (23.07.2003)</b>	Priority date (day/month/year) <b>24 July 2002 (24.07.2002)</b>
International Patent Classification (IPC) or national classification and IPC <b>A61K 31/341, A61P 1/16, 3/10, 35/00, C07D 307/12</b>		
Applicant <b>KOTOSUGI INC.</b>		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>2</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand <b>08 March 2004 (08.03.2004)</b>	Date of completion of this report <b>06 October 2004 (06.10.2004)</b>
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International Application No.

PCT/JP2003/009370

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:

- ☐ international search (under Rules 12.3 and 23.1(b))  
☐ publication of the international application (under Rule 12.4)  
☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ The international application as originally filed/furnished

☒ the description:

pages \_\_\_\_\_ 1-19 \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☒ the claims:

pages \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ 1, 9 \_\_\_\_\_ received by this Authority on \_\_\_\_\_ 08 March 2004 (08.03.2004)

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☒ the drawings:

pages \_\_\_\_\_ 1/6-6/6 \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

☐ the description, pages \_\_\_\_\_

☒ the claims, Nos. \_\_\_\_\_ 2-8 \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages \_\_\_\_\_

☐ the claims, Nos. \_\_\_\_\_

☐ the drawings, sheets/figs \_\_\_\_\_

☐ the sequence listing (*specify*): \_\_\_\_\_

☐ any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International Application No.

PCT/JP 03/09370

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1, 9	YES
	Claims		NO
Inventive step (IS)	Claims	1, 9	YES
	Claims		NO
Industrial applicability (IA)	Claims	1, 9	YES
	Claims		NO

### 2. Citations and explanations

- Document 1: Chinese Pharmaceutical Journal (Taipei), 1997, Vol. 46, No. 3, pages 175-183
- Document 2: Chinese Pharmaceutical Journal (Taipei), 1997, Vol. 49, No. 5-6, pages 285-296
- Document 3: JP 9-208461 A (The Nisshin Oil Mills, Ltd.), 12 August 1997
- Document 4: Bioorganic & Medicinal Chemistry Letters, 1998, Vol. 8, pages 2939-2944

[1] The inventions that are set forth in claims 1 and 9 involve an inventive step in relation to documents 1-4 cited in the international search report.

Document 1 indicates that isotaxiresinol exhibits a hypoglycaemic action. Document 2 indicates that compound 7, which corresponds to formula (1) set forth in the present application, is a lignan, as is isotaxiresinol. Document 3 indicates that the lignans which are represented by general formula (I) are useful in the scavenging of active oxygen species. Document 4 (page 2944, lines 5-7) indicates that in general, active oxygen scavengers are useful as liver protecting agents.

In the written response dated 09 August 2004, the applicant asserts that the fields of chemistry and pharmacology are such that it is impossible to predict the

effects of a substance from the structure thereof; thus, given an example of a single compound, it would be impossible for a person skilled in the art to predict whether the compounds (1) set forth in the present application, which have a chemical structure with a portion that is identical to a portion of the chemical structure of the given compound, will exhibit the same physiological activity as the given compound.

If the disclosures of documents 1-4 are examined in the light of the abovementioned assertion, then it becomes clear that the hypoglycaemic action and the liver-protecting action of the compounds that are represented by formula (I) could not have been predicted by a person skilled in the art in the light of the disclosures of documents 1-4.